



FEB 21 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

PlanMed Oy
% Mr. Bob Pienkowski
Managing Director
PlanMed USA, Inc.
100 North Gary Avenue, Suite A
ROSELLE IL 60172

Re: K021945
Trade/Device Name: PlanMed Sophie and Sophie
Classic (with Digispot and Cytoguide)
Regulation Number: 21 CFR 892.1710
Regulation Name: Mammographic
x-ray system
Regulatory Class: II
Product Code: 90 IZH
Dated: January 30, 2003
Received: February 3, 2003

Dear Mr. Pienkowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

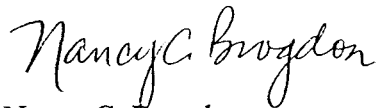
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Planmed Oy

ENCLOSURE 11

510(k) Notification

K021945

Planmed Sophie and Planmed Sophie Classic with digispot and stereotactic biopsy

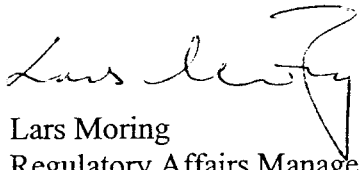
June 7, 2002

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INDICATIONS FOR USE

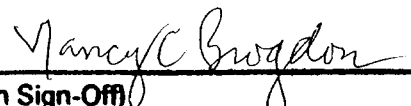
The Planmed Sophie and Planmed Sophie Classic are Mammographic X-ray Systems, which are intended to be used to produce radiographs of the human breast. The devices can be equipped with accessories to fulfil different diagnostic needs, as spot mammography and stereotactic breast needle biopsy.

Helsinki, June 7, 2002



Lars Moring
Regulatory Affairs Manager
Planmed Oy

Prescription Use _____
(Per 21 CFR 801.109)



(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K021945